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11/26/01

Patent
Attorney's Docket No. 002010-685

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

James E. Audia, et al.

Application No.: 09/882,777

Filed: June 14, 2001

For: POLYCYCLIC-A-AMINO-E-CAPROLACTAMS AND RELATED COMPOUNDS

Group Art Unit: 1624

Examiner: Not yet assigned

INFORMATION DISCLOSURE STATEMENT TRANSMITTAL LETTER

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Enclosed is an Information Disclosure Statement and accompanying form PTO-1449 for the above-identified patent application.

[X] No additional fee for submission of an IDS is required.

[ ] The fee of $180.00 (126) as set forth in 37 C.F.R. § 1.17(p) is also enclosed.

[ ] A certification under 37 C.F.R. § 1.97(e) is also enclosed.

[ ] A certification under 37 C.F.R. § 1.97(e), and the fee of $180.00 (126) as set forth in 37 C.F.R. § 1.17(p) are also enclosed.

[ ] Charge $_____ to Deposit Account No. 02-4800 for the fee due.

[ ] A check in the amount of $_____ is enclosed for the fee due.

The Commissioner is hereby authorized to charge any appropriate fees under 37 C.F.R. §§ 1.16, 1.17 and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 02-4800. This paper is submitted in duplicate.

Respectfully submitted,
BURNS, DOANE, SWECKER & MATHIS, L.L.P.

Date: September 10, 2001

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INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

In accordance with the duty of disclosure as set forth in 37 C.F.R. § 1.56, Applicants hereby submit the following information in conformance with 37 C.F.R. §§ 1.97 and 1.98. A copy of each of the following documents was submitted in Application No. 08/337,408, upon which is based a claim for priority under 35 U.S.C.§120. Accordingly, pursuant to 37 C.F.R. 198(d)(1) and (2) a copy of the reference has not been enclosed.

1. U.S. Patent No. 3,598,859, issued August 10, 1971, to Yates, et al.
2. U.S. Patent No. 3,657,341, issued April 18, 1972, to Thorne.
3. U.S. Patent No. 4,080,449, issued March 21, 1978, to Croisier, et al.
4. U.S. Patent No. 4,477,464, issued October 16, 1984, Slade, et al.
5. U.S. Patent No. 4,666,829, issued May 19, 1987, to Glenner, et al.
6. U.S. Patent No. 4,977,168, issued December 11, 1990, to Bernat, et al.
7. U.S. Patent No. 5,238,932, issued August 24, 1993, to Flynn, et al.
8. U.S. Patent No. 5,283,241, issued February 1, 1994, to Bochis, et al.
9. U.S. Patent No. 5,284,841, issued February 8, 1994, to Chu, et al.
10. U.S. Patent No. 5,324,726, issued June 28, 1994, to Bock, et al.
11. U.S. Patent No. 5,360,802, issued November 1, 1994, to Chambers, et al.

12. U.S. Patent No. 5,420,271, issued May 30, 1995, to Warchawsky, et al.
13. U.S. Patent No. 5,478,857, issued December 26, 1995, to Clemens, et al.
14. U.S. Patent No. 5,556,969, issued September 17, 1996, to Chambers, et al.
15. U.S. Patent No. 5,633,251, issued May 27, 1997, to Claremon, et al.
16. U.S. Patent No. 5,658,901, issued August 19, 1997, to Claremon, et al.
17. U.S. Patent No. 5,712,397, issued January 27, 1998, to Esser, et al.
18. U.S. Patent No. 5,770,573, issued June 23, 1998, to Arrhenius, et al.
19. European Patent No. 0 061 187, published September 29, 1982.
20. European Patent No. 0 167 919, published January 15, 1986.
21. European Patent No. 0 284 256, published September 28, 1988.
22. European Patent No. 0 349 949, published January 10, 1990.
23. European Patent No. 0 376 849, published July 4, 1990. (Abstract in English)
24. European Patent No. 0 434 360, published June 26, 1991.
25. European Patent No. 0 434 364, published June 26, 1991.
26. European Patent No. 0 434 369, published June 26, 1991.
27. European Patent No. 0 490 590, published June 17, 1992.
28. European Patent No. 0 514 133, published November 19, 1992.
29. European Patent No. 0 523 845, published January 20, 1993.
30. European Patent No. 0 549 039, published June 30, 1993.
31. European Patent No. 0 647 632, published April 12, 1995.
32. European Patent No. 0 652 009 A1, published June 10, 1995.
33. European Patent No. 0 667 344, published August 16, 1995 (Abstract in English).
34. European Patent No. 0 677 517 A1, published October 18, 1995.
35. European Patent No. 0 732 399 A, published September 18, 1996.
36. European Patent No. 0 778 266 A1, published November 6, 1997.
37. GB 1 519 495, published July 6, 1978.
38. GB 1 573 931, published August 18, 1980.
39. GB 2 272 439, published May 18, 1994.
40. GB 2 290 788 A, published January 10, 1996.
41. JP 04210967 A2, published August 3, 1994.
42. JP 06145148 A2, published May 24, 1994.
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44. JP 10072444 A2, published March 17, 1998.
45. International Publication No. WO 92/01683, published February 6, 1992.
46. International Publication No. WO 92/16524, published October 1, 1992.
47. International Publication No. WO 93/19052, published September 30, 1993.
48. International Publication No. WO 93/19063, published September 30, 1993.
49. International Publication No. WO 94/05693, published March 17, 1994.
50. International Publication No. WO 94/04531, published March 3, 1994.
51. International Publication No. WO 94/07486, published April 14, 1994.
52. International Publication No. WO 94/10569, published May 11, 1994.
53. International Publication No. WO 95/03289, published February 2, 1995.
54. International Publication No. WO 95/03290, published February 2, 1995.
55. International Publication No. WO 95/09838, published April 13, 1995.
56. International Publication No. WO 95/14671, published June 1, 1995.
57. International Publication No. WO 95/21840, published August 17, 1995
58. International Publication No. WO 95/23810, published September 8, 1995.
59. International Publication No. WO 95/25118, published September 21, 1995.
60. International Publication No. WO 95/32191, published November 30, 1995.
61. International Publication No. WO 96/05839, published February 29, 1996.
62. International Publication No. WO 96/16981, published June 6, 1996.
63. International Publication No. WO 96/20725, published July 11, 1996.
64. International Publication No. WO 96/22966, published August 1, 1996.
65. International Publication No. WO 96/40146, published December 19, 1996.
66. International Publication No. WO 96/40653, published December 19, 1996.
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71. International Publication No. WO 97/38705, published October 23, 1997.
72. International Publication No. WO 98/00405, published January 8, 1998.
73. International Publication No. WO 98/25930, published June 18, 1998.
74. International Publication No. WO 98/28268, published July 2, 1998.
75. International Publication No. WO 98/38177, published September 3, 1998.

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78. Bock, et al. "Synthesis and Resolution of 3-Amino-1,3-dihydro-5-phenyl-2*H*-1,4-benzodiazepin-2-ones." *J. Org. Chem.* 52: 3232-3239 (1987).

79. Bock, et al. "An Expedient Synthesis of 3-Amino-1,3-Dihydro-5-Phenyl-2H-1,4-Benzodiazepin-2-one." *Tet. Lets.* 28(9): 939-942 (1987).

80. Chambers, et al. L-708,474: the C5-Cyclohexyl Analogue of L-365,260, A Selective High Affinity Ligand for the CCKB/Gastrin Receptor." *Bioorg. and Med. Chem. Letts.* 3(10):1919-1924 (1993).

81. Chartier-Harlin, et al. "Early-onset Alzheimer's disease caused by mutations at codon 717 of the β-Amyloid precursor protein gene." *Nature.* 353: 844-846 (1991).

82. Citron, et al. "Mutation of the β-amyloid precursor protein in familial Alzheimer's disease increases β-amyloid protein production." *Nature* 360:672-674 (1992).

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84. Evans, et al. "Methods for Drug Discovery: Development of Potent, Selective Orally Effective Cholecystokinin Antagonists." *J. Med. Chem.* 31:2235-2246 (1988).

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86. Finizia, et al. "Synthesis and Evaluation of Novel 1,5-Benzodiazepines as potent and selective CCK-B Ligands, Effect of the Substitution of the N-5 Phenyl with Alkyl Groups." *Bioorg. & Medicinal Chemistry Letters.* 6(24):2957-2962 (1996).

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91. Johnson-Wood, et al. "Amyloid precursor protein processing and $A\beta_{42}$ deposition in a transgenic mouse model of Alzheimer's disease." *PNAS USA*. 94: 1550-1555 (1997).

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98. Patel, et al. "Biological Preperties of the Benzodiazepine Amidine Derivative L-740,093, a Choleycystokinin-B/Gastrin Receptor Antagonist with High Affinity in vitro and High Potency in vivo." *Molecular Pharmacology*. 46:943-948 (1994).

99. Rittle, et al. "A New Amine Resolution Method and its Application to 3-Aminobenzodiazepines." *Tet. Lets.* 28(5):521-522 (1987).

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101. Selkoe, et al., "Amyloid Protein and Alzheimer's Disease." *Scientific American*. 68-78 (1991).

102. Selkoe, et al. "The Molecular Pathology of Alzheimer's Disease." *Neuron*. 6:487-498 (1991).

103. Semple, et al. "Design, Synthesis, and Evolution of a Novel, Selective, and Orally Bioavailable Class of Thrombin Inhibitors: P1-Argininal Derivatives Incorporating P3-P4 Lactam Sulfoamide Moieties." *J. Med. Chem.* 39: 4531-4536 (1996).

104. Semple, et al. "A Facile Large Scale Synthesis of Optically Active 3-Amino-5-(2-Pyridyl)-1,4-Benzodiazepin-2-One Derivatives." *Synthetic Communications.* 26(4): 721-727 (1996).

105. Seubert, et al. "Isolation and quanitification of soluble Alzheimer's peptide from biological fluids." *Nature.* 359: 325-327 (1992).

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107. Showell, et al. "High Affinity and Potent, Water-Soluble 5-Amino-1,4-Benzodiazepine CCKB/Gastrin Receptor Antagonists Containing a Cationic Solubilizing Group." *J. Med. Chem.* 37:719-721 (1994).

108. Smith, et al. "β-APP Processing as a Therapeutic Target for Alzheimer's Disease." *Current Pharmaceutical Design.* 3:439-445 (1997).

109. Van Niel, et al. "CCKB Selective Receptor Ligands: Novel 1,3,5-Trisubstituted Benzazepin-2-ones." *Bioorganic & Medicinal Chemistry Letters.* 5(13):1421-1426 (1995).

110. Varnavas, et al. "Synthesis of New Benzodiazepine Derivatives as Potential Cholecystokinin Antagonists." *Il Farmaco.* 46(2):391-401 (1991).

The information is submitted before the mailing of a first Official Action on the merits, therefore no fee is required under 37 C.F.R. § 1.117(p). In the event a first Office Action is mailed by the United States Patent and Trademark Office prior to receipt of this Information Disclosure Statement, the Commissioner is authorized to debit Deposit Account 02-4880 for the fee required by 37 C.F.R. §1.17(p).

☐ **In accordance with MPEP § 609(c)(2) (February 2000, page 600-107), the Office is requested to return a copy of this Information Disclosure Statement with the Examiner's initials adjacent to this paragraph indicating that this copending application has been considered. By citation to the copending application, confidentiality is not waived and the Office is requested to maintain the confidentiality of the copending application under 35 U.S.C. § 122.**

To assist the Examiner, the documents are listed on the attached form PTO-1449. It is respectfully requested that an Examiner initialed copy of this form be returned to the undersigned.

Respectfully submitted,
BURNS, DOANE, SWECKER & MATHIS, L.L.P.

By: _____
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(650)622-2300

Date:

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INFORMATION DISCLOSURE CITATION

PTO-1449

ATTORNEY'S DKT NO.	APPLICATION NO.
002010-685	09/882,777
APPLICANT: Audia, et al.	
FILING DATE: June 14, 2001	GROUP: 1624

U.S. PATENT DOCUMENTS

EXAMINER'S INITIALS	PATENT NO.	DATE	NAME	CLASS	SUBCLASS	FILING DATE
	3,598,859	8/10/71	Yates, et al.			
	3,657,341	4/18/72	Thorne			
	4,080,449	3/21/78	Croisier, et al.			
	4,477,464	10/16/84	Slade, et al.			
	4,666,829	5/19/87	Glenner, et al.			
	4,977,168	12/11/90	Bernat, et al.			
	5,238,932	8/24/93	Flynn, et al.			
	5,283,241	2/1/94	Bochis, et al.			
	5,284,841	2/8/94	Chu, et al.			
	5,324,726	6/28/94	Bock, et al.			
	5,360,802	11/1/94	Chambers, et al.			
	5,420,271	5/30/95	Warshawsky, et al.			
	5,478,857	12/26/95	Clemens, et al.			
	5,556,969	9/17/96	Chambers, et al.			
	5,633,251	5/27/97	Claremon, et al.			
	5,658,901	8/19/97	Claremon, et al.			
	5,712,397	1/27/98	Esser, et al.			
	5,770,573	6/23/98	Arrhenius, et al.			

FOREIGN PATENT DOCUMENTS

EXAMINER'S INITIALS	PATENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	Translation Yes	Translation No
	0 061 187	9/29/82	Europe				
	0 167 919	1/15/86	Europe				
	0 284 256	9/28/88	Europe				
	0 349 949	1/10/90	Europe				
	0 376 849	7/4/90	Europe (Abstract in English)				

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	0 434 360	6/26/91	Europe				
	0 434 364	6/26/91	Europe				
	0 434 369	6/26/91	Europe				
	0 490 590	6/17/92	Europe				
	0 514 133	11/19/92	Europe				
	0 523 845	1/20/93	Europe				
	0 549 039	6/30/93	Europe				
	0 647 632	4/12/95	Europe				
	0 652 009	8/16/95	Europe				
	0 667 344	8/16/95	Europe (Abstract in English)				
	0 677 517	10/18/95	Europe				
	0 732 399	9/18/96	Europe				
	0 778 266	11/6/97	Europe				
	1 519 495	7/6/78	Great Britain				
	1 573 931	8/18/80	Great Britain				
	2 272 439	5/18/94	Great Britain				
	2 290 788	1/10/96	Great Britain				
	04210967	8/3/94	Japan (Abstract in English)				
	06145148	5/24/94	Japan (Abstract in English)				
	07304770	11/21/95	Japan (Abstract in English)				
	10072444	3/17/98	Japan (Abstract in English)				
	92/01683	2/6/92	WIPO				
	92/16524	10/1/92	WIPO				
	93/19052	9/30/93	WIPO				
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	94/05693	3/17/94	WIPO				
	94/04531	3/3/94	WIPO				
	94/07486	4/14/94	WIPO				
	94/10569	5/11/94	WIPO				

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	95/09838	4/13/95	WIPO				
	95/14671	6/1/95	WIPO				
	95/21840	8/17/95	WIPO				
	95/23810	9/8/95	WIPO				
	95/25118	9/21/95	WIPO				
	95/32191	11/30/95	WIPO				
	96/05839	2/29/96	WIPO				
	96/16981	6/6/96	WIPO				
	96/20725	7/11/96	WIPO				
	96/22966	8/1/96	WIPO				
	96/40146	12/19/96	WIPO				
	96/40653	12/19/96	WIPO				
	96/40654	12/19/96	WIPO				
	96/40655	12/19/96	WIPO				
	96/40656	12/19/96	WIPO				
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	97/38705	10/23/97	WIPO				
	98/00405	1/8/98	WIPO				
	98/25930	6/18/98	WIPO				
	98/28268	7/2/98	WIPO				
	98/38177	9/3/98	WIPO				

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	Aquino, et al. "Discovery of 1,5-Benzodiazepines with Peripheral Cholecystokinin (CCK-A) Receptor Agonist Activity. 1. Optimization of the Agonist "Trigger." *J. Med. Chem.* 39: 562-569 (1996).

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	Bock, et al. "Synthesis and Resolution of 3-Amino-1,3-dihydro-5-phenyl-2*H*-1,4-benzodiazepin-2-ones." *J. Org. Chem.* 52: 3232-3239 (1987).
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	Chambers, et al. L-708,474: the C5-Cyclohexyl Analogue of L-365,260, A Selective High Affinity Ligand for the CCKB/Gastrin Receptor." *Bioorg. and Med. Chem. Letts.* 3(10):1919-1924 (1993).
	Chartier-Harlin, et al. "Early-onset Alzheimer's disease caused by mutations at codon 717 of the β-Amyloid precursor protein gene." *Nature.* 353: 844-846 (1991).
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	Cordell. "B-Amyloid Formation as a Potential Therapeutic Target for Alzheimer's Disease." *Ann. Rev. Pharmacol. Toxicol.* 34:69-89 (1994).
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	Finizia, et al. "Synthesis and Evaluation of Novel 1,5-Benzodiazepines as potent and selective CCK-B Ligands, Effect of the Substitution of the N-5 Phenyl with Alkyl Groups." *Bioorg. & Medicinal Chemistry Letters.* 6(24):2957-2962 (1996).
	Glenner, et al. "Alzheimer's disease: Initial Report of the Purification and Characterization of a Novel Cerebrovascular Amyloid Protein." *Biochem. Biophys. Res. Commun.* 120(3): 885-890 (1984).
	Goate, et al. "Segregation of a missense mutation in the amyloid precursor protein gene with familial Alzheimer's disease." *Nature.* 349: 704-706 (1991).
	Hirst, et al. "Discovery of 1,5-Benzodiazepines with Peripheral Cholecystokinin (CCK-A) Receptor Agonists Activity (II): Optimization of the C3 Amino Substituent." *J. Med. Chem.* 39: 5236-5245 (1996).
	Hofmann, et al. "Interactions of Benzodiazepine Derivatives with Annexins." *J. Biol. Chem.* 273(5):2885-2894 (1998).
	Johnson-Wood, et al. "Amyloid precursor protein processing and $A\beta_{42}$ deposition in a transgenic mouse model of Alzheimer's disease." *PNAS USA.* 94: 1550-1555 (1997).
	Ksander, G.M., et al. "Dual Angiotensin Converting Enzyme/Thromboxane Synthase Inhibitors." *J. Med. Chem.* 37: 1823-1832 (1994).
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	Mullan, et al. "A pathogenic mutation for probable Alzheimer's disease in the APP gene at the N-terminus of β-amyloid." *Nature Genet.* 1: 345-347 (1992).
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EXAMINER	DATE CONSIDERED

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